

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 1842-0029			
<p>I hereby certify that this correspondence is being e-filed or mailed by United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>February 26, 2009</u></p> <p>Signature <u>/Michael D. Beck/</u></p> <p>Typed or printed name <u>Michael D. Beck</u></p>		Application Number 10/749,822			
		Filed December 31, 2003			
		First Named Inventor John Pafford			
		Art Unit 3733			
		Examiner Mary C. Hoffman			
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top; padding: 5px;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>32,722</u></p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p></td><td style="width: 50%; vertical-align: top; padding: 5px;"><p><u>/Michael D. Beck/</u> Signature</p><p><u>Michael D. Beck</u> Typed or printed name</p><p><u>317-638-2922</u> Telephone number</p><p><u>February 26, 2009</u> Date</p></td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>32,722</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>	<p><u>/Michael D. Beck/</u> Signature</p> <p><u>Michael D. Beck</u> Typed or printed name</p> <p><u>317-638-2922</u> Telephone number</p> <p><u>February 26, 2009</u> Date</p>
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<p><input checked="" type="checkbox"/> *Total of <u>3</u> forms are submitted.</p>					

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of :)	
Pafford et al.)	Examiner: Mary C. Hoffman
)	
Serial No. 10/749,822)	Confirmation No. 9366
)	
Filed: December 31, 2003)	Group Art Unit: 3733
)	
Title: Dynamic Spinal)	
Stabilization System)	February 26, 2009

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450
 Sir:

This Pre-Appeal Brief Request is in response to the Final Office Action, mailed on October 29, 2009. Applicant requests a one-month extension of time, to and including February 29, 2009. Payment for the associated fee accompanies this response.

In addition, Applicants are filing herewith a Notice of Appeal and payment for the associated fee.

It is further believed that no further extensions of time or any other fees are currently required; however, if it is determined that a further extension or any additional fees are necessary, Applicants request that the Commissioner grant such extension and deduct the necessary fees from Deposit Account 13-0014.

I hereby certify that this correspondence is being electronically filed via the Electronic Filing System (EFS) of The United States Patent and Trademark Office on February 26, 2009
 (Date of Deposit)

Michael D. Beck
 Name of person filing Document or Fee

/Michael D. Beck
 Signature
February 26, 2009
 Date of Signature

REMARKS

Claims 1, 3-8 and 32 stand finally rejected as anticipated by, and claim 31 as obvious in view of, U.S. Patent No. 5,501,684 to Schlapfer ("Schlapfer"). Claim 31 was rejected as obvious in view of Schlapfer. These rejections are based on a clearly erroneous interpretation of Schlapfer and an improper construction of terms in the pending claims. In particular, an incorrect definition of the term "compress" or "compressible" has been applied and the collet construction of Schlapfer has been incorrectly interpreted as being compressed to adjust flexibility.

For the purposes of this request, Applicants have focused the arguments on claim 1, which is directed to a dynamic spinal stabilization system utilizing a stabilization element, at least two bone anchors with corresponding connectors to connect the bone anchors to the stabilization element. One of the connectors is defined as including: (1) a bearing member attached to the stabilization element; (2) a compressible flexible element supported within the bearing member with the bone anchor extending through the flexible element; and (3) an adjustment element configured to compress the flexible element. The flexible element is recited as permitting pivoting of the bone anchor relative to the stabilization element, and is further defined as "being configured to expand along said longitudinal axis as said [flexible] element is compressed." The adjustment element is defined compressing the flexible element "to thereby adjust the flexibility of said flexible element to adjust the amount of said relative pivoting."

In the office actions, Schlapfer was said to disclose a stabilization element (telescoping segment 37 in FIG. 8), at least two bone anchors (pedicle screws 1e) and at least two connectors (the attachments in FIG. 8). One of the connectors was said to include a bearing member (telescoping member 51) attached to the stabilization element (telescoping segment 37), a compressible flexible element (clamping element 2e in FIG. 8) supported within the bearing element (telescoping member 51), and adjustment element (nut 6e). The structure of the clamping element 2e is not disclosed but it has been assumed that it corresponds to the clamping element 2 shown in FIG. 1.

In rejecting claim 1 as anticipated it was alleged that the clamping element 2/2e permits relative pivoting between the bone anchor 1e and the stabilization element 37 and that this clamping element 2/2e is configured to expand along the longitudinal axis as the element is compressed. It was further suggested that the nut 6e was configured to compress the clamping element 2/2e to thereby adjust the flexibility of the clamping element and further to adjust the amount of relative pivoting. The clamping element 2/2e was said to be "compressed against the inner walls of the borehole ref #31." It was further argued that the clamping element 2/2e is "compressible" because "it presses against the inner walls of the borehole #31 to lock the components together." The clamping element 2/2e was considered to be flexible because it "expands in all directions as a result of its slits to press against the inner walls of the borehole ref #31."

It was further suggested that the nut 6/6a "appears configured to compresses" the clamping element 2/2e to thereby adjust the flexibility of the element "because the adjustment member [nut 6/6e] forces the element [2/2e] to expand and therefore compress against the inner walls of the borehole ref #31." Finally, it was asserted that because the clamping element 2/2e "becomes increasingly tightened until it is locked in the borehole", the adjustment nut [6] "can be considered to adjust the flexibility of the flexible element to adjust the amount of relative pivoting as it produces this tightening/locking action."

First, the Examiner has applied an incorrect definition to "compress" or "compressible" in finding anticipation by Schlupfer. Although a dictionary definition of the word compressible was recited in the office actions, the conclusion regarding the "compressibility" of the clamping element 2/2e is based on the element "pressing" against the inner walls of the borehole 31. As with all collet devices, the collet construction of Schlupfer relies upon friction forces between the expanding collet and the surface against which it expands. Friction is a function of the normal force between the two components – i.e., the amount that one surface "presses" against the other. This is not compression. An element that "presses against" another element is not "compressible" for that

reason. The clamping element 2/2e in Schlapfer does not compress to achieve fixation.¹

Even if this improper definition of "compress" is applied, the clamping element 2/2e of Schlapfer still does not meet the language of claim 1 that requires the element to be "configured to expand ... as said element is compressed." As admitted in the office actions, "the adjustment member [nut 6e] forces the element [2/2e] to expand." As explained in Schlapfer, tightening the nut 6 onto the threaded end 42 of the pedicle screw 1 forces the conical surface 11 into the conical borehole 21 of the clamping element 2, causing it to expand about the slits 24. Col. 5, ll. 12-22. According to the office action, the clamping element 2 does not "compress" until it contacts the inner walls of borehole 31. Thus, as the nut 6 is tightened the clamping element expands without any compression. Moreover, once the clamping element 2 contacts the walls of the borehole it cannot expand, especially if, as alleged in the office action, the clamping element actually compresses during this contact.

Thus, whether the incorrect interpretation of "compress" is applied, or whether the proper meaning of "compress" is utilized, the Schlapfer structure cannot meet the limitations regarding the "compressible flexible element" set forth in claim 1.

Moreover, even if the nut 6/6e is considered to be configured to compress the clamping element 2/2e, the Schlapfer device still cannot "adjust the flexibility" of the clamping element to adjust the amount of relative pivoting." As acknowledged in the office actions, the "flexibility" of the clamping element 2/2e is based on the presence of the slits 24, 27 in the collet-type element. (See, FIG. 2). This "flexibility" is actually produced by bending of the portions of the element at the top of each slit 24. There is nothing in Schlapfer to suggest that the ability

¹ Even if this improper definition is applied, it is clear that Schlapfer does not contemplate any so-called compression in the clamping element. In particular, Schlapfer explains that to improve fixation sharp edges may be added to the surface of the clamping element 2a and the connecting element 3a forming the borehole 31 can be "made of a softer material than clamping element 2a". Col. 5, ll. 59-63.

of the element 2/2e to bend at the slits changes as the nut 6/6e is tightened against the top of the element. Furthermore, until the collet-type element 2/2e contacts the walls of the borehole 31, the element 2/2e and pedicle screw 1 can pivot freely within the telescoping element 51. The only time that this relative movement is prevented is when the element 2/2e is locked within the borehole. But, of course, when the element 2/2e has contacted the borehole, the slits 24, 27 have fully expanded and there is no more bending at the slits. Moreover, if the Examiner's re-definition of "compress" is applied, once this "compression" occurs there can be no more bending of the slits. No matter how the claim terms are construed, the nut 6 in Schlapfer cannot meet the limitation of claim 1 of "an adjustment element configured to compress said flexible element to thereby adjust the flexibility of said flexible element to adjust the amount of said relative pivoting." ²

The very foundation of the anticipation arguments presented in the Final Office Action is flawed and clearly erroneous. Since Schlapfer does not disclose every limitation of Applicants claim 1 it cannot anticipate this claim, or any of its dependent claims. Applicants request withdrawal of the rejections of claims 1-8, 31 and 32.

Respectfully submitted,

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² For the sake of argument, it can be surmised that when the collet-type element 2/2e first contacts the borehole 31 some relative pivoting may occur between the bone screw 1 and the telescoping element 51. When the nut is fully tightened Schlapfer contemplates that the construct is locked so that no relative pivoting can occur. It can thus be assumed that the degree of relative pivoting changes as the nut is tightened from initial contact to total locking. However, this change in the amount of relative pivoting is a function of the friction between the contacting surfaces, which is, of course, a function of the normal force between the surfaces. Any compression of the collet element will necessarily reduce the normal force so that the "compression" alleged by the examiner actually works against the ability to adjust relative pivoting. Nevertheless, this discussion is entirely hypothetical because Schlapfer only contemplates total locking or fixation and does not contemplate any relative pivoting between bone screw and connector.